REMARKS

Claims 13-29 are pending in the instant application. Claims 13-29 have been rejected. Claims 14 and 18 have been amended. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 14-15 under 35 U.S.C. § 112, second paragraph

Claims 14-15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that recitation of "a drug bound to a synthetic receptor selected to bind said drug by a method selected from . . ." is unclear as this may be understood to claim that these are methods by which the drug binds to a synthetic receptor rather that methods for identifying the synthetic receptor.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicant has amended claim 14 to clarify that the methods are used to identify and select the synthetic receptor.

Since similar language also appeared in claim 18, Applicant has also amended this claim to clarify that the methods are used to select the synthetic receptor.

Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims 13-29 under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claims 13-29 under 35 U.S.C. § 102(b) as being anticipated by Morgan, Jr. et al. (U.S. Patent 5,106,951). The Examiner has also maintained the rejection of the claims under 35 U.S.C. § 103(a) over this same reference.

Arguments presented in the last response were found unconvincing. Specifically, the Examiner suggests that the term "immobilized" as set forth in claim 13 is insufficient to overcome these rejections as this term has multiple meanings other than that submitted by Applicant. The Examiner suggests that this term can encompass the drug and conjugate of '951 which are bound to one another or "tied up together", an alternate definition of immobilized. Applicants respectfully disagree.

At the outset, it is respectfully pointed out that the conjugate of the '951 patent is described at column 4, lines 61-67 as comprising:

> a targeting protein such as an antibody or antibody fragment, or carrier molecule; a moiety termed a drug-binding molecule of complimentary structure (abbreviated csDBM and . . .) which is covalently bound to the antibody or carrier; and a drug non-covalently complexed to the csDBM.

Thus, the Examiner's suggestion that the "conjugate and drug" are "tied together" is confusing since the "conjugate" is defined in the '951 patent as comprising the drug. It is therefore difficult to address this rejection and reasoning since it is unclear from the Examiner's statement what is meant by "conjugate". What is clear, however, is that the drug and conjugate of the '951 patent can not be immobilized to one another as the drug is expressly taught to be a component of the conjugate.

Thus, since the '951 patent does not teach or suggest an "immobilized" or "tied together" drug and conjugate, it can neither anticipate nor render obvious claim 13 drawn to an immobilized prodrug complex. Withdrawal of this rejection is therefore respectfully requested.

Further, with respect to pending claims 14-29 of the instant application, each claim recites specific methods for the selection of synthetic receptors which bind to drugs in the prodrug complexes

of the present invention. Specifically, claims 14 and 18 and claims dependent therefrom are drawn to prodrug complexes wherein a synthetic receptor selected to bind to a drug is selected by a method of the group consisting of combinatorial selection, monoclonal antibody selection and antibody engineering. Claims 16, 20, 22, 24, 26 and 28 and claims dependent therefrom are drawn to methods for producing prodrug complexes wherein a synthetic receptor selected to bind to a drug is selected by a method of the group consisting of combinatorial selection, screening and selection of antibodies, engineered antibodies, oligonucleotides or oligosaccharides, or *in vitro* evolution. None of these methods for selecting a synthetic receptor which binds to a drug are taught or suggested by the '951 patent.

The Examiner suggests that the "methods used to identify the conjugate are not considered patentably distinct as they are intended use limitations" and that the antibodies of '951 would be "readily identifiable" by the instant methods. Applicant respectfully disagrees.

At the outset, it is respectfully pointed out that this issue was already addressed by Applicant in great detail in the response filed August 23, 2000. See specifically pages 9-12. However, no mention of Applicant's arguments with respect to this issue was

made by the Examiner in the instant Office Action. Accordingly, it is impossible for Applicant to determine whether these arguments were even considered and, if so, why the rejection is still being maintained.

Contrary to the Examiner's suggestion, the antibodies of the '951 patent would not be identifiable via the claimed methods for selecting a synthetic receptor which binds to the drug, since the antibodies of the '951 patent are not selected based upon their ability to bind a drug. Instead, the complexes of the '951 patent contain an antibody selected based upon its ability to bind a target cell or tissue. In fact, the antibodies of the '951 patent do not even bind to the drug, but rather are linked to the drug via a drug-binding molecule of complementary structure (csDBM) specifically designed to "fit" the drug by combining multiple non-covalent interactions between functional groups on the drug and opposing functional groups on the csDBM.

Further, Applicant fails to see how the specified methods for selection of the synthetic receptor of the present invention comprise an "intended use limitation" not considered patentably distinct by the Examiner. These methods for selecting synthetic receptors relate to production of the claimed complexes, not to use of the complex produced thereby.

Accordingly, Applicant respectfully disagrees with the Examiner's dismissal of this limitation to the claims which clearly distinguishes the present invention from the conjugates taught in the '951 patent. It is also respectfully pointed out that the Examiner's statement in the instant Office Action regarding these methods not being patentably distinct contradicts the Examiner's statement made in the Office Action dated May 23, 2000 at page 3 and again at page 4 wherein the methods used to identify the conjugate were indicated to be patentably distinct.

was a typo

The claimed prodrug complexes and methods for their production, as set forth in this case, comprise different elements and different steps for production than taught or suggested in the '951 patent. Accordingly, this reference neither teaches nor suggests all the limitations of the claimed invention and, thus, can neither anticipate nor render obvious the instant invention.

Withdrawal of these rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) is therefore respectfully requested.

III. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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